

## REMARKS

Claims 1-9, 11-20, 22-24, and 26-47 are presently pending in the case. Claims 41-47 have been added. The new claims are supported by the specification as originally filed. Reconsideration of the present case in view of the remarks herein is requested.

### **Claim rejections under 35 USC §103(a)**

The Examiner rejected claims 1-9, 11-20, 22-24 and 26-40 under 35 USC §103(a) as being unpatentable over U.S. Patent 6,705,313 to Niccolai (hereinafter Niccolai) in view of U.S. Patent 2,946,332 to Sacks (hereinafter Sacks). The rejection is traversed.

Niccolai and Sacks do not render claims 1-9, 15-20, and 22-24 unpatentable. Independent claim 1, for example, is to an aerosolization apparatus comprising, inter alia, a chamber having a sidewall with a cross-section that is non-circular wherein a receptacle contacts the non-circular cross-section of the sidewall when the receptacle moves within the chamber, whereby when a user inhales, air enters into the chamber to cause the receptacle to move within the chamber so that the receptacle is disturbed by the contact with the non-circular cross-section of the sidewall. This positively recited feature is not disclosed by Niccolai. Instead, in the Niccolai device, the receptacle 18 contacts a circular cross-section of the chamber (see Figure 2). Since Niccolai does not disclose each and every feature set forth in claim 1, it does not alone render claim 1 unpatentable. Sacks does not make up for the deficiencies of Niccolai because any combination of Niccolai and Sacks (i) fails to establish a prima facie case under 35 U.S.C. §103(a), (ii) fails to meet the language recited in the claim, and (iii) would not be an obvious modification in that it would render the Niccolai device inoperative.

First, the Examiner's proposed combination of Niccolai and Sacks fails to establish a prima facie case under 35 U.S.C. §103(a). Claim 1 recites a chamber

having a non-circular sidewall that contacts a receptacle when the receptacle moves in the chamber to disturb the receptacle. This chamber configuration is not disclosed in either Niccolai or in Sacks. Niccolai discloses a circular sidewall instead of a non-circular sidewall. Sacks discloses ribs (30) on which a capsule (12) is seated (see column 2 lines 17-20) and a shank (32) which firmly engages the capsule onto the ribs (see column 3 lines 18-22). In Sacks, the capsule does not move in the chamber and is not disturbed by a non-circular cross section. Thus, Sacks does not disclose the claimed chamber configuration. Since neither reference discloses or suggests the claimed chamber configuration, this feature is missing from the proposed combination and the Examiner has failed to establish a prima facie case under 35 U.S.C. §103(a).

Secondly, even if the proposed modification would have been obvious (which it wouldn't have, as described below), the resulting device would not satisfy the language of claim 1. If the Niccolai device were to be modified by adding ribs (30) and shank (32) as taught by Sacks, the capsule within the Niccolai device would be firmly seated thereon and would not move during a user's inhalation. Thus, several positively recited claim limitations in claim 1 would not be met. For example, claim 1 recites, "wherein the chamber is sized to receive a receptacle containing a pharmaceutical formulation in a manner which allows the receptacle to move within the chamber"; "wherein the receptacle contacts the non-circular cross-section of the sidewall when the receptacle moves within the chamber"; and "whereby when a user inhales, air enters into the chamber through the inlet to cause the receptacle to move within the chamber so that the receptacle is disturbed by the contact with the non-circular cross-section of the sidewall." A device as modified by the Examiner's proposal would not meet at least these limitations. Accordingly, the Examiner has further failed to establish a prima facie case, even assuming the proposed modification were to be made.

Thirdly, it would not have been obvious to one having ordinary skill in the art to make the modification proposed by the Examiner because doing so would go against the teachings of Niccolai and would render the Niccolai device inoperative. The aerosolization of the medicament in the capsule of Niccolai is achieved by lifting,

rotation, and shaking of the capsule caused by the airflow through the chamber (see column 3 lines 40-58). With the Examiner's proposed modification, the capsule would be seated and not able to move and thus not able to be lifted, rotated, and shaken. Thus, there would be little or no aerosolization achieved. Furthermore, the Sacks aerosolization mechanism is based on the entrainment of medicament as air flows into the capsule and out the other end of the capsule whereas Niccolai only punctures one end of the capsule. Therefore, if the capsule is seated in Niccolai, there is nowhere for the aerosolized medicament to flow. For at least these reasons, a person of ordinary skill in the art would not have found it obvious to incorporate the teachings of Sacks into the device of Niccolai. Withdrawal of the rejections under 35 U.S.C. §103(a) is requested.

Claims 2-9 and 11-14 are also not rendered unpatentable by Niccolai and Sacks. Claims 2-9 and 11-14 depend from claim 1 and are not rendered unpatentable by Niccolai and Sacks for at least the same reasons as the claim from which they depend. Withdrawal of the rejections under 35 USC §103(a) is requested.

Niccolai and Sacks also do not render independent claim 15 unpatentable. Claim 15 is to an aerosolization apparatus comprising, inter alia, a chamber sized to receive a receptacle containing a pharmaceutical formulation in a manner which allows the receptacle to move within the chamber, wherein the chamber has a sidewall with a cross-section that is non-circular and wherein the receptacle contacts the non-circular cross-section of the sidewall when the receptacle moves within the chamber, whereby when a user inhales, air enters into the chamber to cause the receptacle to move within the chamber so that the receptacle is disturbed by the contact with the non-circular cross-section of the sidewall. Niccolai does not disclose these positively recited features. Sacks does not make up for the deficiencies of Niccolai in that Sacks also does not disclose the chamber configuration claimed and because it would not have been obvious to one having ordinary skill in the art to modify Niccolai with the teachings of Sacks, as discussed above. Accordingly, claim 15 is not properly rejected under 35 U.S.C. §103(a), and Applicant requests withdrawal of the rejection.

Claims 16-20 and 29-32 are also not rendered unpatentable by Niccolai and Sacks. Claims 16-20 and 29-32 depend from claim 15 and are not rendered unpatentable by Niccolai and Sacks for at least the same reasons as the claim from which they depend. Withdrawal of the rejections under 35 USC §103(a) is requested.

Niccolai and Sacks also do not render independent claim 22 unpatentable. Claim 22 is to an aerosolization apparatus comprising, inter alia, a chamber sized to receive a receptacle containing a pharmaceutical formulation in a manner which allows the receptacle to move within the chamber wherein the chamber has a sidewall with a cross-section that is non-circular and wherein the receptacle contacts the non-circular cross-section of the sidewall when the receptacle moves within the chamber, whereby when a user inhales, air enters into the chamber to cause the receptacle to move within the chamber so that the receptacle is disturbed by the contact with the non-circular cross-section. Niccolai does not disclose these positively recited features. Sacks does not make up for the deficiencies of Niccolai in that Sacks also does not disclose the chamber configuration claimed and because it would not have been obvious to one having ordinary skill in the art to modify Niccolai with the teachings of Sacks, as discussed above. Accordingly, claim 22 is not properly rejected under 35 U.S.C. §103(a), and Applicant requests withdrawal of the rejection.

Claims 23, 24 and 33-36 are also not rendered unpatentable by Niccolai and Sacks. Claims 23, 24 and 33-36 depend from claim 22 and are not rendered unpatentable by Niccolai and Sacks for at least the same reasons as the claim from which they depend. Withdrawal of the rejections under 35 USC §103(a) is requested.

Niccolai and Sacks also do not render independent claim 26 unpatentable. Claim 26 is to a method of aerosolizing a pharmaceutical formulation, the method comprising, inter alia, inserting a receptacle into a chamber having a non-circular cross section and causing the receptacle to move about the non-circular cross section to aerosolize the pharmaceutical formulation. Niccolai does not disclose aerosolization by

causing a receptacle to move about a non-circular cross section. Sacks does not make up for the deficiencies of Niccolai in that Sacks also does not disclose the aerosolization mechanism claimed and because it would not have been obvious to one having ordinary skill in the art to modify Niccolai with the teachings of Sacks, as discussed above. Accordingly, claim 26 is not properly rejected under 35 U.S.C. §103(a), and Applicant requests withdrawal of the rejection.

Claims 27, 28 and 37-40 are also not rendered unpatentable by Niccolai and Sacks. Claims 27, 28 and 37-40 depend from claim 26 and are not rendered unpatentable by Niccolai and Sacks for at least the same reasons as the claim from which they depend. Withdrawal of the rejections under 35 USC §103(a) is requested.

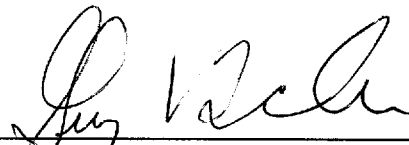
## Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

JANAH & ASSOCIATES

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